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6 510(K) SUMMARY

SEP 7 2012

Submitter Information

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Date Prepared:	June 28, 2012

Device Name

Device Trade Name: Arrow PICC powered by Arrow VPS Stylet
Common Name, Catheter: Peripherally Inserted Central Catheter (PICC)
Common Name, Stylet: Catheter, Ultrasound, Intravascular

Classification Name, Catheter: Percutaneous, implanted, long-term intravascular catheter per 21 CFR: 880.5970
Classification Name, Stylet: Diagnostic Intravascular Catheter per 21 CFR 870.1200

Predicate Devices

- K103255: Vascular Positioning System (VPS System) Stylet
- K113277: ArrowADVANTAGE5 Pressure Injectable Peripherally Inserted Central Catheter (PICC)
- K080604: Pressure Injectable PICC

Device Description

The Arrow PICC powered by Arrow VPS Stylet has the following characteristics:

- 4 Fr, 1-Lumen, 40-55 cm catheter preloaded with VPS Stylet
- 5 Fr, 2-Lumen 40-55 cm catheter preloaded with VPS Stylet
- 6 Fr, 3-Lumen 40-55 cm catheter preloaded with VPS Stylet

The Arrow PICC is pre-loaded with the Arrow VPS Stylet and will be provided in sterile kit configurations.

The Arrow Pressure Injectable PICC is a short-term or long-term, single use catheter designed to provide access to the central venous system. It consists of a non-tapered, radiopaque

polyurethane extruded catheter body with a softer, contoured Blue Flex Tip. The catheter can be used for the injection of contrast media.

The Arrow VPS Stylet is a polyimide tube containing a Doppler sensor on a coax cable and an intravascular electrocardiogram (ivECG) signal sensing stainless steel wire. The Doppler sensor and the exposed portion of the ivECG are located at the distal end of the stylet and are used to detect and transmit physiological information to the VPS Console for analysis. The proximal end contains a connector to the VPS Console or to an extension cable that in turn connects to the VPS Console. The stylet was designed to be able to be inserted and removed from any catheter with a luminal diameter of at least 0.021 inch. For user convenience, Arrow has created the Arrow PICC powered by Arrow VPS Stylet in which the Arrow PICC is provided pre-loaded with the Arrow VPS Stylet.

Indications for Use and Intended Use

The Pressure Injectable PICC is indicated for short or long term peripheral access to the central venous system for intravenous therapy, blood sampling, infusion, power injection of contrast media and allows for central venous pressure monitoring. The maximum pressure of power injectors used with the pressure injectable PICC catheter may not exceed 300 psi. The maximum pressure injection flow rate ranges from 4 ml/sec to 6 ml/sec. Refer to the product specific labeling for the maximum pressure injection flow rate for the specific lumen being used for pressure injection.

The VPS Stylet and Console are indicated for guidance and tip positioning for central venous catheters. The Stylet provides stiffness for use in placement of the catheter, intravascular capability for ECG detection and recording and intravascular ultrasound for catheter guiding and positioning. The VPS Stylet, when used with the VPS Console, provides real-time catheter tip location information by using the patient's physiological (cardiac electrical activity and blood flow) information. When the VPS System guidance indicator shows a blue bullseye, the catheter tip is in the desired location.

The VPS System is indicated for use as an alternative method to fluoroscopy or chest x-ray for central venous catheter tip placement confirmation in adult patients when a steady blue bullseye is obtained. NOTE: If a steady Blue Bullseye is not obtained, standard hospital practice should be followed to confirm catheter tip location.

Limiting but not contraindicated situations for this technique are in patients where alterations of cardiac rhythm change the presentation of the P-wave as in atrial fibrillation, atrial flutter, severe tachycardia and pacemaker-driven rhythm, and in central venous catheterization procedures performed through femoral or saphenous vein access which change the presentation of the P-wave. In such patients, who are easily identifiable prior to central venous catheter insertion, the use of an additional method is required to confirm catheter tip location.

Technological Characteristics and Substantial Equivalence

The Arrow PICC powered by Arrow VPS Stylet is substantially equivalent to the Vascular Positioning System (VPS System) Stylet (K103255), ArrowADVANTAGE[5] Pressure Injectable Peripherally Inserted Central Catheter (PICC) (K113277) and the Pressure Injectable PICC (K080604) in terms of indications for use, design, manufacturing process, functional performance, and materials of construction. The subject device combines the predicate Arrow VPS Stylet and the Arrow Pressure Injectable PICCs; there is no change to the previously cleared devices or their indications for use.

Nonclinical Testing

The results of the catheter performance testing: tensile strength, and burst and the stylet performance testing: tensile, Hi-pot, Continuity and removal testing demonstrate that the Arrow PICC powered by Arrow VPS Stylet is as safe, as effective and performs comparably to the predicate VPS stylet and Pressure Injectable PICC.

Conclusions

The predicate and the subject devices have the same indications for use, intended use, design, materials, and are manufactured using the same processes. The results of the testing performed have demonstrated that combining the two previously cleared devices does not raise new issues of safety or effectiveness and therefore the combination is considered substantially equivalent to the cited predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 7 2012

Arrow International, Inc.
c/o Ms. Elizabeth Duncan
Sr. Regulatory Affairs Specialist
2400 Bernville Road
Reading, PA 19605

Re: K121941
Trade/Device Name: Arrow PICC powered by Arrow VPS Stylet
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous Implanted Long-Term Intravascular Catheter
Regulatory Class: Class II
Product Code: LJS, OBJ
Dated: August 29, 2012
Received: August 30, 2012

Dear Ms. Duncan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): _____

Device Name: **Arrow PICC powered by Arrow VPS Stylet**

Indications for Use:

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Prescription Use ___ X ___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121941